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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,644	09/27/2001	Mark W. Bitensky	S-092701	3052

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EXAMINER	
SPIEGLER, ALEXANDER H	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,644	BITENSKY ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *19-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

1. This action is in response to Applicants' response, filed on March 5, 2004. Currently, claims 1-46 are pending, Claims 1-18 remain rejected, and Claims 19-46 have been withdrawn.

2. This action is made FINAL. Any objections and rejections not reiterated below are hereby withdrawn. Specifically, the 112, 2nd paragraph rejection has been withdrawn in view of Applicants' arguments.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutton et al. (Microvascular Research (1997) 53: 272-281).

Regarding Claim 1, Sutton teaches an array comprising a plurality of microchannels for capturing an individual cell (see abstract, pg. 274 and Fig. 6, for example).

Regarding Claim 2, Sutton teaches the array comprises at least a first and a second set of microchannels (both having cross sectional areas), wherein said first cross sectional area is larger than said second cross sectional area, and wherein said microchannels form a gradient for

capturing said cell (see Fig. 1 and pg. 278, for example) (teaching differing width lengths for the microchannels, thus teaching an array having one larger and one smaller cross-sectional area).

Regarding Claims 3-8, 12-14 and 18, Sutton teaches "substantially wedge-shaped" microchannels having a depth of 3.2 um, a width of between 3-4 um, and a length of 100 um (see pg. 278, column 1, for example) (the entry and exit portions are inherent to Sutton's microchannels). Furthermore, absent a specific definition of "about", the dimensions taught by Sutton are considered to encompass the dimensions of the microchannels claimed in Claims 5-8. Likewise, with respect to Claim 18, Sutton teaches a plurality of sets of microchannels having dimensions that are encompassed by the recitation of "about" (see Figs. 1, 6 and pg. 278, for example).

Regarding Claims 9-10, Sutton teaches the microchannels are adapted to prevent a cell from escaping from said microchannels and that the microchannels have a width of between "about" 1.5 to "about" 0.5 microns and a length of between "about" 0.5 to "about 30 microns (pgs. 274-276, for example).

Regarding Claims 11 and 15-16, Sutton teaches that said microchannels are adapted to maintain a constant rate of fluid flow therethrough and that Sutton's array further comprises a means of moving cells through the microchannels (e.g., negative pressure by connected water columns (pgs. 275-276 and 278, for example).

Regarding Claim 17, Sutton teaches that the microchannels are used to simulate the dimensions of human capillaries (see title and abstract, for example).

Applicants' Arguments

Applicants' argue:

1) Sutton teaches measuring the transit of cells through microchannels, and in no way captures cells as required by Claim 1. See pages 9-10 of Applicants' arguments.

2) Sutton's microchannels, while of differing widths, do not form a gradient, as depicted in Figure 2 of the present invention. See page 10 of Applicants' arguments.

3) Sutton does not contemplate variation within a single channel, whereas the instant invention comprises microchannels that are "substantially wedge-shaped", as depicted in Figure 3B, which vary in their dimensions within a single channel. See page 11 of Applicants' arguments.

Response to Applicants' Arguments

Applicants' arguments have been considered, but are not persuasive for the following reasons:

1) Sutton teaches that cells are "captured" in the microchannels, since Sutton teaches that individual cells flow throw the microchannels, and are thus contained and "captured" within the microchannels of Sutton's device. For example, in Figure 5, Sutton demonstrates that single cells are flowing through the channel array. These single cells are considered to be "captured" within the microchannel, since these cells are contained within the microchannel. The specification does not provide any definition or teaching as to what is encompassed by "capturing", and therefore, Sutton's microchannels are interpreted as "capturing" the cell therein, since, for example, these cells are trapped within the microchannels. Applicants' argue the claimed array captures the cell by static measurement, whereas Sutton measures the velocity of a cell as it moves through a microchannel. (See Applicants' response on page 9). Even assuming

this is true, Claim 1 is not drawn to taking a static measurement of a cell; Claim 1 is drawn to an array comprising a plurality of microchannels for capturing an individual cell therein.

2) The recitation of "gradient" is not defined in the specification, nor is there a clear indication that "gradient" as recited in Claim 2, should be interpreted to mean gradient array (20) of Figure 2, as Applicants' appear to be suggesting. That is, the recitation of "gradient" does not distinguish the array of the present invention over the array of Sutton because neither the Claims, nor the specification define "gradient" to mean any specific dimension, structure or arrangement of channels.

3) The recitation of "substantially wedge-shaped" is not defined in the specification, nor is there a clear indication that "substantially wedge-shaped" as recited in Claim 4, should be interpreted to mean the wedge shape depicted in Figure 3B, as Applicants' appear to be suggesting. That is, the recitation of "substantially wedge-shaped" does not distinguish the microchannels of the present invention over the microchannels of Sutton because neither the Claims, nor the specification define "substantially wedge-shaped" to mean any specific dimension or structure or that there is a particular variation of dimensions within a single channel.

Accordingly, because Applicants' arguments have not been found to be persuasive, the rejection is maintained.

5. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Brody et al. (Biophysical J. (1995) 68(6) 2224-2232).

Regarding Claim 1, Brody teaches an array comprising a plurality of microchannels for

capturing an individual cell (see abstract, pgs. 2224-2225 and Figs. 1-4, for example).

Regarding Claim 2, Brody teaches the array comprises at least a first and a second set of microchannels (both having cross sectional areas), wherein said first cross sectional area is larger than said second cross sectional area, and wherein said microchannels form a gradient for capturing said cell (see pgs. 2225-2226 and Figs. 1-4, for example) (teaching differing width lengths for the microchannels, thus teaching an array having one larger and one smaller cross-sectional area).

Regarding Claims 3-8, 12-14 and 18, Brody teaches "substantially wedge-shaped" microchannels having a depth of 4 um, a width of between 2.5 to 4 um, and a length of 12, 13 or 20 um (see pgs. 2225-2227 and Figs. 1-4, for example) (the entry and exit portions are inherent to Brody's microchannels). Furthermore, absent a specific definition of "about", the dimensions taught by Brody are considered to encompass the dimensions of the microchannels claimed in Claims 5-8. Likewise, with respect to Claim 18, Brody teaches a plurality of sets of microchannels having dimensions that are encompassed by the recitation of "about" (see pgs. 2225-2227 and Figs. 1-4, for example).

Regarding Claims 9-10, Brody teaches the microchannels are adapted to prevent a cell from escaping from said microchannels and that the microchannels have a width of between "about" 1.5 to "about" 0.5 microns and a length of between "about" 0.5 to "about 30 microns (pgs. 2226-2227, for example).

Regarding Claims 11 and 15-16, Brody teaches that said microchannels are adapted to maintain a constant rate of fluid flow therethrough and that Brody's array further comprises a

means of moving cells through the microchannels (e.g., negative pressure by connected water columns (pgs. 2226-2227, for example).

Regarding Claim 17, Brody teaches that the microchannels are used to simulate the dimensions of human capillaries (see pg. 2224, for example).

Applicants' Arguments

Applicants' argue that like Sutton, Brody, does not teach capturing the cell or that the channels are wedge-shaped or form a gradient.

Response to Applicants' Arguments

Applicants' arguments have been considered, but are not persuasive for the following reasons. Like Sutton, Brody teaches that cells are "captured" in the microchannels, since Brody teaches that individual cells flow throw the microchannels, and are thus contained and "captured" within the microchannels of Brody's device. For example, in Figures 2 and 5, Brody demonstrates that single cells are flowing through the channel array. These single cells are considered to be "captured" within the microchannel, since these cells are contained within the microchannel. Furthermore, the specification does not provide any definition or teaching as to what is encompassed by "capturing", and therefore, Brody's microchannels are interpreted as "capturing" the cell therein, since, for example, these cells are trapped within the microchannels.

The recitation of "gradient" is not defined in the specification, nor is there a clear indication that "gradient" as recited in Claim 2, should be interpreted to mean gradient array (20) of Figure 2, as Applicants' appear to be suggesting. That is, the recitation of "gradient" does not distinguish the array of the present invention over the array of Brody because neither the Claims,

nor the specification define "gradient" to mean any specific dimension, structure or arrangement of channels.

The recitation of "substantially wedge-shaped" is not defined in the specification, nor is there a clear indication that "substantially wedge-shaped" as recited in Claim 4, should be interpreted to mean the wedge shape depicted in Figure 3B, as Applicants' appear to be suggesting. That is, the recitation of "substantially wedge-shaped" does not distinguish the microchannels of the present invention over the microchannels of Brody because neither the Claims, nor the specification define "substantially wedge-shaped" to mean any specific dimension or structure or that there is a particular variation of dimensions within a single channel.

Accordingly, because Applicants' arguments have not been found to be persuasive, the rejection is maintained.

Conclusion

6. No claims are allowable.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Effenhauser et al. (Anal. Chem. (1997) 69: 3451-3457)

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander H. Spiegler
June 4, 2004

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